PATENT
70063-00004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thienna Ho Serial No.: 10/599,779 Filed: 06/28/2007 Title: SKIN LIGHTENING METHOD	Art Unit: 1617 Examiner: Gina Yu

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

The appellant filed a Notice of Appeal in the above-identified application on August 27, 2010 under 35 U.S.C. § 134(a). The appellant requests entry, consideration, and favorable action on this appeal at the Office's earliest convenience.

In accordance with Rule 41.37(c), the appellant presents the following items under the headings prescribed therein.

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Real Party in Interest

Thienna Ho, an individual residing in California, owns the subject application.

Related Appeals and Interferences

None.

Status of Claims

The Official Action mailed on May 28, 2010 (hereinafter the "Final Action"), finally rejected claims 1, 4-6, 9-11, 13, 15, 17 and 19. Claims 2-3, 7-8, 12, 14, 15 and 18 were cancelled prior to the Final Action. No other claims are pending.

Status of Amendments

All amendments to the pending claims were submitted and entered prior to the Final Action.

Summary of Claimed Subject Matter

This section includes a concise explanation of the subject matter defined in the independent claim involved in the appeal (i.e., claim 1), which includes references to the specification and drawings as specified in Rule 41.37. What is disclosed in the specification are embodiments of the corresponding claim elements.

Claim 1 defines a *method for causing a person to develop a skin tone noticeably lighter than the person's natural skin tone comprising:*

(A) *"delivering an effective amount of methyl sulfonyl methane to a person for developing a lighter skin tone by ingestion of the effective amount, at least until the person develops a skin tone noticeably lighter than before commencement of the*

delivery step, wherein the effective amount comprises orally administered doses in an amount of at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months." Please see, for example, p. 1, line 28 to p. 2, line 15; p. 6, lines 13-22; Table I, p. 7.

Grounds of Rejection To Be Reviewed on Appeal

Review of the following grounds of rejection is sought on appeal:

The rejection of claims 1, 4-6, 9-11, 13, 15, 17 and 19 under 35 U.S.C. § 103(a) as being unpatentable over Herschler (Pat. No. 4,296,130) in view of Webster's Ninth New Collegiate Dictionary (1991) (hereinafter, "Websters") and Salim (WO 1994/05279. Claims 4-6, 9-11, 13, 15, 17 and 19 stand or fall with base claim 1.

Argument

In the arguments below, the appellant presents reasons why defined groups of claims are separately patentable over the cited references.

Rejections of Claims 1, 4-6, 9-11, 13, 15, 17 and 19 Under 35 U.S.C. § 103

Claim 1 defines "*delivering an effective amount of methyl sulfonyl methane to a person for developing a lighter skin tone by ingestion of the effective amount, at least until the person develops a skin tone noticeably lighter than before commencement of the delivery step.*" Claim 1 further defines that "*the effective amount comprises orally administered doses in an amount of at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months.*" The

combination of Herschler, Websters and Salim fails to disclose or make obvious both of these elements defined by claim 1.

It is undisputed that Herschler discloses that compositions including methyl sulfonyl methane (MSM) can be "used effectively to soften skin, to dilute blood, and for a variety of other useful purposes." Col. 2:18-21. It is also undisputed that Herschler discloses oral administration of MSM to rats in an amount of 20 grams per kilogram per day for six weeks, to demonstrate non-toxicity only and not to show any efficacious result. Example 16 at col. 11. It is acknowledged that Herschler does not disclose oral administration of MSM in the dosage defined by the present claim. Final Action, p. 3. The Final Action relies heavily on Herschler's disclosure that:

> MSM has proved to have varied and useful properties when applied to any animal tissue subject to undesired chemical bond formation including cross-linking. It has been observed to beautify the complexion, to enhance scalp and hair, and generally to help make the body of the user more flexible and comfortable.

Col. 2:29-35. Based on this passage and on a dictionary definition of "complexion" the Final Action found that:

> It would have been obvious to one of ordinary skill in the art at the time of the present invention that the Herschler method of administering MSM to human subjects would bring about changes to, and/or improve, the color and skin tone and/or overall appearance of the skin because the reference teaches MSM "beautifies the complexion" of the skin, and the Webster dictionary indicates that complexion refers to the color or appearance of skin in the cosmetic art. Thus applicant's claim of development of "a skin tone noticeably lighter than the person's natural skin tone" by administering MSM to the patient would naturally flow from practicing the Herschler method, which would have been observed by one of ordinary skill in the art.

Final Action, p. 3-4. These findings constitute reversible error, for the reasons discussed below.

First, although "complexion" has different meanings that can include skin tone, in the context of Herschler it does not refer to skin tone. Instead, the phrase "beautify the complexion," as used by Herschler clearly refers to the cosmetic effect of providing the skin a softer, smoother texture and more youthful appearance. See, e.g., col. 2:29-34 (MSM "useful when applied to any animal tissue subject to undesired chemical bond formation"); col. 3:15-17 ("effective in softening, smoothing or comforting the skin"); col. 3:31-34 ("soften, smooth and lubricate the skin"); col. 3:36-37 ("resist cross-linking of collagen"); col. 7:15-19 ("the softness and pliancy associated with youthful, healthy skin thus can be maintained"); col. 7:62-64 (a substantial softening and smoothing of the skin was observed"); and col. 10:1-2 ("noted a substantial improvement in skin softness, smoothness and comfort." Herschler contains absolutely no discussion of skin color or tone. Therefore one or ordinary skill, upon reading Herschler, would have concluded that MSM is useful for beautifying the skin by rendering it more pliable and smoother, or by reducing irritation, but would not have received the slightest suggestion that MSM might alter natural skin color in any way.

Herschler's failure to disclose or suggest any lightening of skin tone by use of the phrase "beautify the complexion" or otherwise is confirmed by two declarations already of record in this application: The Declaration of Dr. Nikolay N. Barashkov ("Barashkov") and The Declaration of Sherilee J. Backman ("Backman"). Ms. Backman, being a

cosmetic chemist, represents someone with the background and experience of one "of ordinary skill in the art." Dr. Barashkov's background in physical and organic chemistry may also be relevant, and is worthy of consideration as from one of skill in the art. Ms. Backman confirms the appellant in that the finding in the Final Action "does not accurately reflect what would have been obvious to a cosmetic chemist when the present patent application was first filed as an international application in April 2005." Backman ¶ 5. Dr. Barashkov confirms that "[t]he phrase "beautify the complexion," which is mentioned by Herschler as one of applications for methylsulfonylmethane (MSM), undoubtedly refers to providing the skin a softer, smoother texture and appearance," and would not have suggested lightening skin tone. Barashkov ¶ 4-5. Moreover, both organic and cosmetic chemists would have understood the phrase "beautify the complexion" as used by Herschler to refer only to the softening and smoothing effect of MSM that Herschler described, and not to any skin lightening effect. Barashkov ¶ 6-8; Backman ¶ 7.

In addition, the entire disclosure of Herschler shows absolutely no recognition or conception that MSM has any effect on skin tone. "The Herschler patent does not anywhere disclose or imply that MSM lightens skin tone or coloration. . . Among other things, at the time the Herschler patent was written (1979) and even much later it was not known that MSM exhibited a tone-lightening effect on skin." Barashkov ¶ 5. In addition, Ms. Backman declares that:

It is self-evident from his disclosure that Herschler had not conceived of

> using MSM for skin lightening or brightening and therefore could not have used the phrase "beautify the complexion" to refer to any such effect. For example, Herschler does not mention vitiligo, hyperpigmentation, or any other disease affecting skin color, at all. His patent is focused on the stabilization of urea (carbamide) by combining it with MSM, and using this combination to "beautify the complexion" by softening and smoothing the skin. In column 3 of his patent, he writes "An object is to provide a stable, neutral vehicle for pharmaceuticals, which vehicle has no interfering or undesirable pharmacological activity." Furthermore, if Herschler were interested at all in skin lightening, he would have mentioned hydroquinone, or some other known skin lightening agent, in his table of "actives" in column 13. The fact that he mentions no such agent evidences his lack of knowledge or interest in skin lightening as an effect of his cosmetic compositions

Backman ¶ 6. The testimony of Dr. Barashkov and Ms. Backman, in light of the disclosure of Herschler and Webster's definition of "complexion," persuasively shows that Herschler fails to disclose or suggest "delivering an effective amount of methyl sulfonyl methane to a person for developing a lighter skin tone by ingestion of the effective amount, at least until the person develops a skin tone noticeably lighter than before commencement of the delivery step." The testimony of these chemists demonstrates that Webster's dictionary definition of "complexion" in combination with Herschler would not have suggested the use of MSM to lighten or change skin tone. The reasoning stated in the Final Action to the contrary is evidently based on an erroneous finding, and the rejection of claim 1 should therefore be reversed.

The Final Action does not argue that any dose regimen taught by Herschler would inherently result in lightening of skin tone, and appellant is not aware of any basis supporting such a finding. On the contrary, as acknowledged in the Final Action, Herschler also fails to disclose "wherein the effective amount comprises orally

administered doses in an amount of at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months," as also defined by claim 1. Final Action, p.3. The Final Action erroneously cites Salim as disclosing this element, and the error in the finding is demonstrated below. It is undisputed that Salim fails to disclose or suggest that MSM or anything else can be used to lighten skin tone, and is not generally concerned with skin tone.

Salim discloses an oral dose of MSM in units of 100 to 500 mg "at intervals of from 2 to 8 hours, most preferably every 6 hours" for therapeutic purposes such as healing injured skin, in combination with a sulfur-containing amino acid. Salim, p. 7 first paragraph; Backman ¶ 9. A cosmetic chemist of ordinary skill would understand Salim as disclosing a maximum dose of MSM in the range of 1500-2000 mg per day (500 mg three or four times daily, or smaller doses more frequently), in combination with one or more sulfur-containing amino acids in the same dosage range. Backman ¶ 9. For a 45 kg adult female, Salim therefore discloses a maximum dose of MSM in the range of 33 to 44 mg/kg/day. Backman ¶ 9. Therefore, a reasonable reading of Salim leads to the conclusion that Salim taught maximum oral doses of MSM significantly less than claimed.

Moreover, there would have been no motivation for someone reading Herschler and Salim to discover the dose regimen defined by claim 1, because lower doses were already known to be effective for all known cosmetic and therapeutic applications, as demonstrated by the Herschler and Salim references. Backman ¶ 10. There was no

suggestion that higher doses of MSM would produce any beneficial effect, so there would have been no reason to experiment with higher doses. Id. For example, Salim teaches that increasing the concentration of MSM does not provide any additional benefit in reducing tissue injury, as reported in its tables on pages 11 and 13. Therefore, Salim provides no incentive to experiment with higher doses, and if anything, might have discouraged such experimentation by reporting that increased concentrations of MSM provide no additional benefit. Backman ¶ 11; Salim p. 11-13.

In addition, MSM's skin lightening effects would not have been considered expected or predictable at the time these effects were first reported by appellant in the present application. Backman ¶ 8. Skin lightening is an unexpected result of administering MSM. Barashkov ¶ 9.

In summary of the foregoing, the evidence shows that the combination of Herschler, Webster's and Salim fails to disclose each and every element of claim 1. The references and enclosed declarations also show that those of skill in the art would have had no motivation to administer the claimed oral doses. In addition, the declarations show that the skin lightening effect provided by the claimed dose regimen would have been unexpected. Claim 1 therefore recites a combination of elements that was not known, would not have been obvious at the time the invention was made, and which leads to an unexpected result. The Final Action does properly support any findings contrary to the foregoing.

In view of the deficiencies of Herschler, Webster's and Salim outlined above,

these references pose no bar to patentability of claim 1, which is therefore allowable. The remaining claims 4-6, 9-11, 13, 15, 17 and 19 are also allowable, at least as depending from an allowable base claim.

Conclusion

In view of the foregoing, Appellant respectfully requests the reversal of the rejection of currently pending claims 1, 4-6, 9-11, 13, 15, 17 and 19, and allowance of these claims forthwith.

Appendices

Appealed claims 1, 4-6, 9-11, 13, 15, 17 and 19 are attached hereto as Appendix A. Evidence for consideration in this appeal is attached hereto as Appendix B. Related Appeals and Interferences, if any, are listed in Appendix C.

Respectfully submitted,

Date: November 1, 2010

/Jonathan Jaech/
Jonathan Jaech for Appellant
Reg. No. 41,091

CUSTOMER NUMBER

58688
PATENT TRADEMARK OFFICE

Connolly Bove Lodge & Hutz LLP
333 South Grand Avenue
Suite 2300
Los Angeles, CA 90071-1560
(213) 787-2500

APPENDIX A

APPEALED CLAIMS

1. (Previously presented) A method for causing a person to develop a skin tone noticeably lighter than the person's natural skin tone, comprising delivering an effective amount of methyl sulfonyl methane to a person for developing a lighter skin tone by ingestion of the effective amount, at least until the person develops a skin tone noticeably lighter than before commencement of the delivery step, wherein the effective amount comprises orally administered doses in an amount of at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months.

2-3. (Canceled)

4. (Previously presented) The method of claim 1, further comprising delivering the effective amount of methyl sulfonyl methane by periodically ingesting in a compound comprising methyl sulfonyl methane and other ingredients.

5. (Original) The method of claim 4, further comprising delivering the effective amount of methyl sulfonyl methane by ingesting the compound further comprising at least one nutrient selected from vitamins, minerals, antioxidants, proteins, and amino acids.

6. (Previously presented) The method of claim 1, further comprising delivering the effective amount of methyl sulfonyl methane also by periodic topical application of a compound comprising methyl sulfonyl methane.

7. (Canceled).

8. (Canceled)

9. (Previously presented) The method of claim 1, further comprising delivering a portion of the effective amount of methyl sulfonyl methane in a compound comprising about 1 to 20 weight percent methyl sulfonyl methane for topical application.

10. (Previously presented) The method of claim 1, further comprising delivering a portion of the effective amount of methyl sulfonyl methane in a compound comprising greater than about 20 weight percent methyl sulfonyl methane for topical application.

11. (Previously presented) The method of claim 1, further comprising delivering a portion of the effective amount of methyl sulfonyl methane in a compound comprising about between about 20 to 22 weight percent methyl sulfonyl methane for topical application.

12. (Canceled)

13. (Original) The method of claim 1, further comprising delivering an exfoliate to the person during the delivery of the methyl sulfonyl methane.

14. (Canceled)

15. (Original) The method of claim 6, further comprising delivering an exfoliate to the person during the delivery of the methyl sulfonyl methane.

16. (Canceled)

17. (Original) The method of claim 1, wherein the delivering the effective amount of methyl sulfonyl methane is performed at least about daily.

18. (Canceled)

19. (Original) The method of claim 6, wherein the delivering the effective amount of methyl sulfonyl methane is performed at least about daily.

20. (Canceled)

APPENDIX B

EVIDENCE

The Declaration of Dr. Nikolay N. Barashkov ("Barashkov") and

The Declaration of Sherilee J. Backman ("Backman")

70063-00004

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thienna Ho	Art Unit: 1617
Serial No.: 10/599,779	
Filed: 06/28/2007	Examiner: Gina Yu
Title: SKIN LIGHTENING METHOD	

Declaration Under 37 CFR Section 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

I, the undersigned Dr. Nikolay N. Barashkov, declare and say:

1. I have more than thirty years of experience in area of spectral research in chemistry and medico-biological applications, both in academia and industry, including specialty chemicals, biotechnology, as well as food and animal feed industry, and have applied for and obtained numerous patents in my field. I hold doctoral degrees in Organic Chemistry and Polymer Chemistry and in Polymer Chemistry and Physical Chemistry from the Karpov Institute of Physical Chemistry in Moscow, Russia. Further details concerning my academic training, work experience, publications and activities are presented in my résumé attached as Exhibit A to the present declaration.

2. I have received no compensation in exchange for submitting this

declaration, and have no personal interest or stake in the outcome of the above-referenced patent application.

3. I have reviewed and am familiar with the above-referenced patent application, Serial No. 10/599,779, Skin Lightening Method. I have also reviewed U.S. Patent No. 4,296,130 ("Herschler") and the most recent office action of the present application, dated November 13, 2009.

4. The phrase "beautify the complexion," which is mentioned by Herchler as one of applications for methylsulfonylmethane (MSM), undoubtedly refers to providing the skin a softer, smoother texture and appearance. Softening was evidently important to Herschler because it is expressly named in the second of only two total claims of the Herschler patent. The Herschler patent also discusses the softening and smoothing skin effect of MSM in numerous places, and claims that MSM provides anti-aging benefits for skin by making skin more pliable (i.e., softer).

5. The Herschler patent does not anywhere disclose or imply that MSM lightens skin tone or coloration. Instead, with respect to skin the Herschler patent repeatedly discloses only that MSM makes skin softer, smoother and more pliable. If Herschler had intended "beautify the complexion" to also refer to lightening skin tone, he would have expressly described a tone lightening effect. Among other things, at the time the Herschler patent was written (1979) and even much later it was not known that MSM exhibited a tone-lightening effect on skin. Therefore this effect could not have been presumed from the general phrase "beautify the complexion," absent any explicit disclosure of a skin tone lightening effect by Herschler.

6. The word "complexion" has no special technical meaning in organic or physical chemistry relevant to the appearance of skin.

7. The word "complexion" may itself have several possible meanings from ordinary use. From my experience in the ordinary use of English, people sometimes refer to a "light complexion" or a "dark complexion" when referring to skin tone. However a phrase like "beautiful complexion" would not be considered as referring to skin tone, because beauty is not considered limited to skin of a particular color by most people. In fact many in America would have considered (and still would consider) it offensive or racist to imply that skin of a lighter color is "more beautiful" than skin of a darker color. Therefore, a chemist of ordinary skill writing a patent application in 1979 would not have used "beautify the complexion" to refer to lightening skin tone, first of all because the phrase would not have been understood in the intended way, and second of all because use of the phrase to mean lightening skin tone would have risked offending the reader.

8. For the reasons explained in the foregoing paragraphs, an organic chemist of ordinary skill, upon encountering the phrase "beautify the complexion" in the Herschler patent would have understood the phrase to refer only to the softening and smoothing effect of MSM that Herschler described, and not anything else.

9. From my experience and training in organic and physical chemistry, I am not aware of MSM or any similar substance being known or recognized as capable of lightening skin tone when administered to a human or animal. Skin lightening is an unexpected, not predictable result of administering MSM that was first reported, so far as I know, by the inventor of the present patent application Serial No. 10/599,779.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false

statements may jeopardize the validity of the application of any patent issued thereon.

Respectfully submitted,

Date: December 7, 2009

Dr. Nikolay N. Barashkov

EXHIBIT "A"

Dr. Nikolay N.Barashkov

SUMMARY

30+ years of experience in area of spectral research (mainly fluorescent research) in chemistry and medico-biological applications, both in academia and industry, including specialty chemicals, biotechnology, as well as food and animal feed industry. Proven ability to apply knowledge of organic chemistry and physical chemistry, simultaneously work on multiple batches of high complexity and recommend process improvements in such areas, as preparation of dozens new fluorescent dyes-monomers, and hundred new polymers, identification and characterization of prepared compounds by HPLC, NMR, FTIR, MS, GPC, UV-Vis, fluorescent spectroscopy and other physico-chemical methods. Team player who works well with others and has good skills in writing proposals. Has desire to learn and ability to adapt well to new projects and environments.

PROFESSIONAL EMPLOYMENT AND EXPERIENCE

Micro Tracers, Inc, San Francisco, CA
Director of R&D and Technical Services 01/2006-Present
Applied research and development in the areas of chlorine-free methods for sterilization of contaminated waters, as well as creation of new microtracers, including nanosized microtracers.

*Created new chlorine-free electrolytic and photochemical methods for sterilization of contaminated waters (presentation at two ACS Meetings, 2006 and 2007, submitted SBIR Proposal for EPA);

*Developed new alumina-based and silica gel-based microtracers for feed and pharmaceutical industries;

*Created ferromagnetic nanoparticles suitable for making liquid microtracers;

*Provided analytical support in characterization of existing iron-based microtracers, as well as selenium-based products manufactured by Micro Tracers, Inc.

ANRESCO Laboratories, San Francisco, CA
Senior Consulting Chemist 10/2005-12/2005
HPLC analysis of aflatoxins and vitamins

Biotium,Inc, Hayward, CA 2004-2005
Senior Scientist

Applied research in the area of the synthesis of small molecules, such as fluorescent dyes and related biochemical reagents for life science and drug discovery, as well as in the area of protein chemistry:

*Developed new Ethidium Homodimer III which is capable to form the fluorescent complexes with double-strained DNA and has higher binding affinity compared to known homodimers

*Proposed improved synthetic procedures for making fluorescent calcium indicators; membrane potential dyes; fluorogenic alkaline phosphatase substrates; bioluminescent enzyme substrates; fluorogenic peptidase substrates; biotin derivatives used as the cellular tracers.

* Developed QC procedures, including HPLC and NMR evaluation of final products.

Radiant Color, Richmond, CA 1997-2004
Senior Research Scientist
Applied research, scale-up and development in the areas of small molecules, such as fluorescent dyes, fluorescent polymers and polymer-dye compositions:

*Planed and prioritized numerous projects; managed all aspects of the development process being a leader of the technical group consisting of one Senior Chemist and two technicians.

*Handled scale-up processes in-house to supply new fluorescent pigments on 50-80 lbs scale.

*Proposed and developed new methods of fluorescent dyes' modification by incorporation of functional groups (together with Keystone Aniline Corporation and Advanced Synthesis, Inc).

*Proposed and carried out new synthetic routes for making fluorescent pigments with improved color development and high level of lightfastness (2 US patents and 3 European patents granted).

*Created method for preparation of spherical nanoparticles (size below 150 nanometers) of polymer -dye compositions for ink jet technology and military application (US patent pending, submitted Proposal for STTR Program of DoD).

*Investigated photophysical behavior of organic compounds which show unique aggregation-induced emission from nanoparticles (size 40-120 nm) (Together with Institute of Nano Science and Technology, Hong Kong, US Patent Pending , submitted NSF Proposal).

*Developed new polyester-based hybrid material for sensor application containing crystals of triboluminescent Eu-complex (2 US patents pending, submitted Proposal for SBIR Program of NASA).

*Co-authored 8 published articles, 9 patents and presented 7 papers at international and national conferences.

University of Texas at Dallas, Department of Chemistry, Dallas, TX 1994-1997
Research Scientist
Basic and applied research, development and analysis of new small molecules, such fluorescent monomers and model compounds, and light-emitting polymers:

*Developed new vinylenearylene, terthiophene, benzimidazole and benzoxazole derivatives.

*Created and investigated new poly(dialkoxyarylenevinylene)s for producing new materials for flat panel display technology.

*Developed new method of synthesis for aromatic polyamides and polyesters with chromophor fragments in the chain which have studied as materials for light-emitting diode applications.

*Characterized new materials using HPLC, FT-IR, NMR, MS, UV-Vis, luminescence, GPC.

*Trained undergraduate and graduate students to use methods that have been developed.

*Co-authored 15 published articles and presented eight papers at international and national conferences.

Texas Tech University, Department of Physics, Lubbock, TX 1993-1994
Visiting Associate Professor
Research and development of new polymeric materials for use in scintillator devices:

*Created method of preparation for epoxypolymer-dye compositions to produce new ultrafast plastic scintillators and wavelength shifters.

*Characterized new polymer-dye compositions by using time-resolved fluorescent technique.

*Taught physics undergraduate courses.

*Co-authored published 3 articles and presented paper at national meeting.

Fermi National Accelerator Laboratory, Batavia, IL 1993
Visiting Scientist
Research and development of new radiation stable polymeric materials for plastic scintillators:

*Developed new copolymers of styrene with luminophore fragments in the chain and polystyrene-dye compositions that proved to be effective new plastic scintillators.

*Created method of preparation for epoxypolymer scintillators with improved radiation stability.

*Evaluated scintillation efficiency and spectral properties of new plastic scintillators.

*Co-authored published article and presented paper at international conference.

Karpov Institute of Physical Chemistry, Moscow, Russia
1978-1994

Head of Chemistry Group

Basic and applied research, development and laboratory management in the area of small molecules, such as new reactive fluorescent dyes, and light-emitting polymers on their base, including investigation of proteins, containing fluorescent labels:

*Proposed new multistep synthetic routes for making fluorescent dyes with different reactive groups.

*Investigated photophysical properties of proteins containing fluorescent sulfopyrene moieties.

*Invented about eighty new colored and fluorescent polymers using copolymerization and copolycondensation techniques.

*Commercialized new polymer-based materials (films, fibers, composites) with unique optical properties and high photo- and radiation stability.

*Provided supervision of 6 Ph.D. and 4 M.S. students.

*Authored 6 books, 75 published articles and 25 Russian Invention's Certificates.

PUBLICATIONS

Six books (two of them "Fluorescent Polymers" and "Luminescence in Public Health" were published in English, four - in Russian), 95 published articles , 26 Russian Inventor's Certificates, two US patents and three European patents granted and 8 US patents pending.

EDUCATION

2nd Phd (Degree of Doctor of Sciences in Polymer Chemistry and Physical Chemistry). Dissertation "Preparation of polymers with predicted spectral-luminescent properties by chemical modification of the molecular chain"
Karpov Institute of Physical Chemistry, Moscow,
Russia 1991

1st Ph.D. (Organic Chemistry and Polymer Chemistry). Dissertation "Synthesis and izomerization cyclization of aromatic polycyanoamides and polycyanoureas"
Karpov Institute of Physical Chemistry, Moscow,
Russia 1978

M.S. (Chemical technology of organic synthesis). Institute of Fine Chemical Technology, Moscow, Russia 1975

PROFESSIONAL AFFILIATIONS AND RELATED ACTIVITIES

American Chemical Society 1995
Visiting Lecturer of Department of Chemistry at UNC at Charlotte 2003
Visiting Professor of Department of Chemistry at Eurasian National University, Astana, Kazakhstan 2005-Present
The winner of 10 InnoCentive Challenges who has been nominated among 11 other most successful InnoCentive Solvers with a Title "Top Solver of the Year 2007" and among 17 other most successful InnoCentive Solvers with a Title "Top Solver of the Year 2008" 2007-2009
(see web site http://www.innocentive.com/servlets/project/ProjectInfo.po?s=AW).

PERSONAL

US Citizen 2002

70063-00004

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thienna Ho	Art Unit: 1617
Serial No.: 10/599,779	
Filed: 08/28/2007	Examiner: Gina Yu
Title: SKIN LIGHTENING METHOD	

Declaration Under 37 CFR Section 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

I, the undersigned Sherilee J. Backman, declare and say:

1. I am a cosmetic chemist with over twenty years of technical experience in the cosmetics industry. My expertise includes formulating new products, including skincare, color, cosmetics, hair care, OTC drugs, and many other product types; assisting in and troubleshooting cosmetics manufacturing; providing technical documentation supported by experimental data; and communicating with customers as a liaison for various interest groups. I studied Biology as an undergraduate at Rensselaer Polytechnic Institute in Troy, NY; I later graduated from Rutgers College, Rutgers University, in NJ with a B.A. in Political Science. I have served as an Adjunct Professor for core courses in the Masters Program in Cosmetic Science at Fairleigh Dickinson University in Teaneck, NJ, and hold several patents in the area of novel raw material applications in cosmetic formulations. Further details concerning my academic

training, work experience, and activities are presented in my résumé attached as Exhibit A to the present declaration.

2. I have reviewed the present patent application, Serial No. 10/599,779, Skin Lightening Method. I have also reviewed U.S. Patent No. 4,296,130 ("Herschler") and the office action of the present application dated November 13, 2009 discussing Herschler and other prior art references.

3. I reviewed the Herschler patent to determine whether it might disclose the concept of using methylsulfonylmethane (MSM) to lighten skin tone. Herschler discloses other uses of MSM for treating the skin, but does not in any way disclose or suggest that MSM is capable of lightening a subject's skin tone.

4. I reviewed the office action dated November 13, 2009 concerning the rejection of claim 1 for obviousness over Herschler, Webster's Ninth New Collegiate Dictionary's definition of "complexion," and International Patent Publication WO/1994/005479 ("Salim"). The examiner found Herschler's disclosure that MSM could be used to "beautify the complexion," together with a definition of "complexion" as "the color or appearance of skin," would have made it obvious to use MSM to lighten skin tone. This finding does not accurately reflect what would have been obvious to a cosmetic chemist when the present patent application was first filed as an international application in April 2005, as more fully explained below.

5. Herschler's use of the word "complexion" is limited only to the phrase "beautify the complexion." A cosmetic chemist of ordinary skill would not have understood "beautify the complexion" as used by Herschler to mean "lightening the skin tone." Instead, one of ordinary skill would have believed that to beautify the complexion meant to improve the skin's appearance by a cosmetic effect such as softening and smoothing. Herschler is limited to disclosing cosmetic effects of MSM, such as

softening and smoothing. In contrast, lightening the skin tone is more of a physiological effect, is not disclosed or discussed by Herschler at all, and is of a different nature than softening and smoothing.

6. It is self-evident from his disclosure that Herschler had not conceived of using MSM for skin lightening or brightening and therefore could not have used the phrase "beautify the complexion" to refer to any such effect. For example, Herschler does not mention vitiligo, hyperpigmentation, or any other disease affecting skin color, at all. His patent is focused on the stabilization of urea (carbamide) by combining it with MSM, and using this combination to "beautify the complexion" by softening and smoothing the skin. In column 3 of his patent, he writes "An object is to provide a stable, neutral vehicle for pharmaceuticals, which vehicle has no interfering or undesirable pharmacological activity." Furthermore, if Herschler were interested at all in skin lightening, he would have mentioned hydroquinone, or some other known skin lightening agent, in his table of "actives" in column 13. The fact that he mentions no such agent evidences his lack of knowledge or interest in skin lightening as an effect of his cosmetic compositions.

7. Even in isolation, that is, outside of the context of Herschler, to "beautify" the skin complexion would not have been understood as meaning or suggesting lightening of skin tone to a cosmetic chemist, because various cosmetics are known to both lighten and darken skin in pursuit of a more beautiful complexion. That is, to "beautify" does not imply either lightening or darkening of skin tone. Instead, to refer to making the overall skin tone lighter, a cosmetic chemist would have used the terms "lightening" or "brightening" the skin tone or complexion.

8. I have experience in the production and use of products for skin lightening and brightening, including products based on hydroquinone, ascorbic acid and its derivatives (including but not limited to various ascorbyl phosphates, ascorbyl glucoside, and other ascorbyl esters), kojic acid, and plant extracts including but not limited to those of arbutin, licorice and mulberry. These ingredients and combinations thereof, like MSM, are used to lighten skin tone. As a cosmetic chemist developing skin lighteners, I considered various alternatives and prospective substances to achieve skin lightening, without discovering any reference to MSM as a prospective skin lightener. In addition, the Herschler and Salim references contain nothing that would have led me to consider trying MSM as a prospective skin lightening agent. There is nothing in these references or otherwise reported in the prior art that I am aware of to suggest that MSM might have been expected to possess skin lightening properties. MSM's skin lightening effects as first reported by the inventor of the present application would therefore not have been considered expected or predictable at the time these effects were first reported by her in the present application.

9. Claim one of the present application is limited to "at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months." The references Herschler and Salim do not specifically disclose this dose regimen. Salim discloses an oral dose of MSM in units of 100 to 500 mg "at intervals of from 2 to 8 hours, most preferably every 6 hours" for therapeutic purposes such as healing injured skin, in combination with a sulfur-containing amino acid. Salim does not disclose a specific duration of treatment, a dose per unit of body weight, or a skin lightening effect. A cosmetic chemist of ordinary skill would understand Salim as disclosing a maximum dose of MSM in the range of 1500-2000 mg per day (500 mg three or four times daily, or smaller doses more frequently), in combination with one or more sulfur-containing amino acids in the same dosage range. For a relatively small 45 kg adult female, this equates to a maximum dose of MSM in the range of 33 to 44

mg/kg/day, which is much less than the at least 133 mg/kg/day specified in claim 1 of the present application.

10. One of ordinary skill reading Herschler and Salim would not have been motivated to discover the higher dose range specified in claim 1, for several reasons. First, lower doses were already known to be effective for all known cosmetic and therapeutic applications, as demonstrated by the Herschler and Salim references. Second, there was no suggestion that higher doses of MSM would produce any beneficial effect, much less skin lightening. One of ordinary skill would therefore have had no apparent reason to experiment with higher doses.

11. In addition, the Salim reference is focused on the synergistic effect of sulfur-containing amino acids with MSM, predominately but not exclusively by topical administration. Most important, Salim demonstrated that increasing the concentration of MSM alone does not provide any additional benefit in reducing tissue injury. Specifically, in the tables reported on pages 11 and 13 of Salim, no additional benefit is shown for increasing concentration of MSM past 5% in ethanol administered orally. Therefore, Salim provides no incentive to experiment with higher doses, and if anything, might have discouraged such experimentation by reporting that increased concentrations of MSM provide no additional benefit.

12. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Respectfully submitted,

Date: January 12, 2010

Sherilee J. Backman

EXHIBIT "A"

Sherilee J. Backman

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Qualifications Over twenty years of technical experience in the cosmetics industry. Strong skills in formulating very creative and innovative products, troubleshooting the manufacturing process, as well as in customer communication and oral and written presentations. Experienced in formulating skincare, color, cosmetics, haircare, OTC drugs, and many other products. Experienced in start-to-finish personal product development and commercialization. Adept at management, ingredient sales and distribution, and targeted marketing.

Experience

2008–Current *Venus of Vermont, Inc.* *Brattleboro, VT*

Technical Director

- Provide technical, sales and marketing expertise to select customers in the cosmetics and nutraceuticals arenas.

2004–2007 *DKSH North America, Inc.* *Baltimore, MD*

Business Unit Manager, Personal Care & Food Ingredients

- Managed personal care and cosmetic, and food, beverage and nutraceutical ingredient product lines.
- Performed sales, marketing and technical services.
- Expanded client and product bases with multi-tiered marketing and sales strategies.
- Visited key customers, established subdistributors, agents and strategic alliances, and contracted materials suppliers.
- Covered territory of US, Canada and Central America.
- Coordinated services to multinational clients; established global pricing and resolved regulatory compliance issues.
- Sourced novel and unique raw materials for representation; found and evaluated principals and materials; helped develop and shared marketing and technical information; wrote contracts; participated on the DKSH PCI New Product Development team.
- Proposed establishment of a regional technical service division.
- Wrote and monitored divisional budgets totaling above $3 million in sales.
- Established and coordinated logistics efforts; established warehousing and built costs into product price positions.
- Communicated with international colleagues daily.
- Developed advertising and company brand image awareness.
- Increased gross sales in cosmetics materials by nearly 60% within two years.
- Expanded cosmetic ingredient portfolio exponentially within two years.

1997–2004 *SJH Consulting, Inc.* *Germantown, MD*

President

- Provide cosmetic formulations, raw materials evaluations, and sourcing for goods and services.
- Guide product commercialization and production.
- Assist start-ups any way possible.

1998–2004 *Fairleigh Dickinson University* *Hackensack, NJ*

Adjunct Professor

- Teach Skin Care and Hair Care Formulation, and Raw Materials Evaluation, lecture courses for the School of Natural Sciences Master's program in cosmetic sciences.

1998–2000 *Cosmetech Laboratories, Inc.* *Fairfield, NJ*

Vice President

- Provided formulation and raw material evaluation guidance to customers and staff.
- Promoted customer relations with innovative technology.

1996–1997 *Presperse Inc.* *Piscataway, NJ*

Technical Manager

- Managed full-service supplier laboratory and staff.
- Oversaw QC, applications, technical service and sampling functions.
- Designed and oversaw experimental raw material evaluations.
- Established standard operational procedures in the laboratory.

1993–1996 *Rona®/EM Industries* *Hawthorne, NY*

Senior Applications Chemist

- Provided prototype formulations and oversaw substantiation testing.
- Devised technical programs for new and existing raw materials.
- Helped establish materials specifications.
- Provided technical service to customers.
- Wrote and assessed supplier literature.

Affiliations and Honors

SCC; CTFA Sunscreen Task Force and Steering Committee. RPI Honors List, Rutgers Deans List; member, Alpha Sigma Lambda Honors Fraternity; NYSCC Chapter Historian, patent holder.

Skills

- Successfully pitch product approaches and materials to customers.
- Create innovative and patent-able product formulations
- Provide assistance in start-to-finish product commercialization.
- Formulate, both from scratch and from prototype, a wide variety of cosmetic systems throughout the range of skincare, haircare, color cosmetic and treatment products (q.v. attached listing).
- Color-matching.
- Trouble-shoot production/manufacturing process.
- Provide customer technical support, including developing presentations.
- Versatile in computer software applications.
- Able to perform accurate benchwork quickly and efficiently.
- Coordinate multiple groups of people and projects.

Products developed include:

Skin Care	daily use moisturizing creams and lotions for body, hands, face, feet, undereye, etc. moisturizing gels and serums water-in-oil and water-in-silicone barrier creams and lotions body mousses alpha- and beta-hydroxy products mixed emulsions liquid crystal emulsions low-energy emulsions spray emulsions baby products cleansing milks, creams, toners NPA-approved and certified organic products
Hair Care	shampoos 2-in-1 and 3-in-1 shampoos conditioners hair repair and glossing products hair gels hair sprays (natural pump and aerosol) hair mousses perms depilatories temporary and semi-permanent hair dyes hair mascaras anti-dandruff preparations dry shampoos heat-activated preparations
Color Cosmetics	emulsion foundations (oil-in-water, water-in-oil, water-in-silicone, mixed) anhydrous foundations and concealers transfer-resistant foundations and concealers fine-line-minimizing foundations and powders pressed powder wet/dry foundations eyeshadows (pressed and anhydrous) moisturizing lipsticks extended wear lipsticks transfer-resistant lipsticks lipglosses conditioning mascaras waterproof mascaras lash-extending, building, and curling mascaras brow mascaras liquid eyeliners blushers (pressed powder and anhydrous)

loose powders

	edible body paint
	children's nail enamel
Ethnic Products	skin lightening creams, lotions, gels and serums
	facial and undereye lighteners
	skin clarifiers and brighteners
	dry skin emulsions
	hair relaxers
	facial depilatories
	hair styling pomades, gels, creams, sprays
	hair glossing and managing preparations
	make-up foundations
	pressed-powder blushes
	lipsticks
Spa Products	bath salts
	bath oils
	bath and shower cleansers
	scrub emulsions, gels, salts
	massage oils, gels, bars
	aromatherapy emulsions, balms, oils, salts
	clay and mud emulsions and masques
	preparations with incorporated encapsulates, herbs
Treatment, Hygiene, and OTC Drug Products	organic and inorganic sunscreen emulsions, sticks, gels, sprays, oils and solutions from SPF 2-50+
	children's sunscreen products
	water- and sweat-resistant sunscreen products
	self-tanner emulsions, gels, sprays
	insect repellent emulsions, oils, sprays
	nail and cuticle treatment creams, gels, balms
	depilatories
	skin lighteners
	toothpastes
	mouthwashes
	vaginal lubricants
	skin protectant creams, lotions, mousses
	anti-acnes lotions, creams, make-up foundations, blotters and concealers
	medicated washes
	cleansing wipes
	anti-cellulite emulsions and gels
	lip balms
	oil-control preparations
	stick, roll-on, gel, and clear antiperspirants

	deodorants

	topical analgesic emulsions, gels, sticks
	tooth bleaching systems
Fragrances and Ancillaries	perfumes, colognes, edp's, edt's, aftershaves
	moisturizing fragrances
	clear fragrance sticks
	fragrance balms and pomades
	bubble colognes
	line-extension creams, lotions, gels, cleansers

APPENDIX C

RELATED APPEALS AND INTERFERENCES

NONE.